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CALIFORNIA STEM CELL
TREATMENT CENTER, INC.,
CELL SURGICAL NETWORK
CORPORATION, ELLIOT B. LANDER,
and MARK BERMAN

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
EASTERN DIVISION**

UNITED STATES OF AMERICA.

Plaintiff,

V.

CALIFORNIA STEM CELL
TREATMENT CENTER, INC., a
California corporation, CELL
SURGICAL NETWORK
CORPORATION, a California
corporation, and ELLIOT B. LANDER,
M.D., MARK BERMAN, M.D.,
individuals,

Defendants.

CASE NO. 5:18-CV-01005-JGB-KK

Hon. Jesus G. Bernal
Riverside, Courtroom 1

DEFENDANTS' ANSWER TO COMPLAINT

Action Filed: May 9, 2018
Trial Date: None Set

Defendants California Stem Cell Treatment Center, Inc., Cell Surgical Network Corporation, Elliot B. Lander, and Mark Berman (“Defendants”), by and through their attorneys, hereby respond to the allegations in the numbered paragraphs of the Complaint filed by Plaintiff United States of America (“Plaintiff”) as follows:

6 1. This paragraph contains legal conclusions and does not require an
7 answer. To the extent an answer is required, Defendants deny the allegations in this
8 paragraph, and specifically deny that Defendants' procedures are subject to
9 regulation under the FDCA.

Jurisdiction and Venue

11 2. This paragraph contains legal conclusions and does not require an
12 answer. To the extent an answer is required, Defendants deny the allegations in this
13 paragraph.

14 3. This paragraph contains legal conclusions and does not require an
15 answer. To the extent an answer is required, Defendants deny the allegations in this
16 paragraph.

Defendants and their Operations

18 4. Admit.

19 5. Defendants admit that they conduct procedures involving extraction
20 from a patient and reintroduction into the same patient of stromal vascular fraction
21 using a patient's own adipose tissue ("SVF procedure"), and further admit that they
22 previously conducted procedures involving Vaccinia Vaccine, Live and SVF
23 expanded in culture. Defendants otherwise deny the remaining allegations
24 contained in the paragraph, including the characterization of the SVF as
25 "manufactured," and of the SVF procedure as a "product."

26 6. This paragraph contains legal conclusions and does not require an
27 answer. To the extent an answer is required, Defendants deny the characterization
28 of the SVF procedure as a “product.” admit that the SVF procedure involves

1 extraction from a patient and reintroduction into the same patient of stromal
2 vascular fraction, and specifically deny that Defendants' procedures are subject to
3 regulation under the FDCA.

4 7. Defendants deny the characterization of the SVF procedure as a
5 "product," deny the characterization of the SVF procedure as an "experimental
6 treatment," and further deny that the SVF procedure has been used to treat
7 diabetes, but otherwise admit the allegations in this paragraph.

8 8. Defendants deny the characterization of the SVF procedure as a
9 "product," and deny that SVF procedures involve injection into the brain or spinal
10 cord, but otherwise admit the allegations in this paragraph.

11 9. Defendants deny that the SVF procedure "is the result of a multi-step
12 manufacturing process," and further deny the characterization of the SVF
13 procedure as a "product," but otherwise admit the remaining allegations contained
14 in the paragraph.

15 10. Defendants deny that the SVF procedure involves "numerous
16 processing steps," and deny the characterization of the SVF as "manufactured," but
17 otherwise admit the remaining allegations contained in this paragraph.

18 11. Defendants deny the allegations contained in the first sentence of this
19 paragraph, but otherwise admit the remaining allegations contained in this
20 paragraph.

21 12. Defendants deny the characterization of the SVF procedure as a
22 "product," and further deny the allegations contained in the first and second
23 sentences of this paragraph. Defendants otherwise admit the remaining allegations
24 contained in this paragraph. Defendants specifically deny that Defendants'
25 procedures are subject to regulation under the FDCA.

26 13. Defendants deny the first sentence of this paragraph. Defendants
27 further deny the characterization of the SVF procedure as a "product," deny the
28 characterization of the SVF procedure as a "manufacturing process," and deny the

1 characterization of 0.9% Sodium Chloride Injection, USP and 5% Dextrose in
2 Lactated Ringer's as "components." Defendants admit that the collagenase used in
3 their procedures is received from Indiana. Defendants otherwise lack sufficient
4 knowledge or information to form a belief as to the truth of remaining allegations
5 in this paragraph and therefore deny them.

6 14. Defendants deny the characterization of the procedure as an
7 "experimental treatment," as well as the characterization of the procedure as
8 "manufacturing." Defendants otherwise admit the allegations contained in the
9 second, third, and fifth sentences of this paragraph. Defendants further admit that
10 they previously conducted procedures involving a combination of SVF and
11 Vaccinia Vaccine, Live. The fourth sentence contains legal conclusions and does
12 not require an answer. To the extent an answer is required, Defendants admit the
13 allegations in the fourth sentence of this paragraph. Defendants otherwise deny the
14 remaining allegations contained in this paragraph.

15 15. Defendants deny the characterization of the procedure as
16 "manufactured," but otherwise admit the remaining allegations contained in this
17 paragraph.

18 16. Defendants admit that they previously recovered adipose tissue and
19 sent said tissue to a licensed facility as part of the expanded SVF procedure, and
20 the resulting ATCELL was then returned to CSCTC Rancho Mirage and CSCTC
21 Beverly Hills. Defendants otherwise deny the remaining allegations contained in
22 this paragraph.

23 17. Defendants deny the characterization of the SVF procedure as a
24 "product," and deny the characterization of the procedure as a "treatment," but
25 otherwise admit the remaining allegations contained in this paragraph.

26 18. Defendants deny the characterization of the SVF procedure as a
27 "product," and specifically deny that Defendants' procedures are subject to

28

1 regulation under the FDCA, but otherwise admit the remaining allegations
 2 contained in this paragraph.

3 19. Defendants deny the characterization of the SVF procedure as a
 4 “product,” and specifically deny that Defendants’ procedures are subject to
 5 regulation under the FDCA, but otherwise admit the remaining allegations
 6 contained in this paragraph.

7 20. Defendants deny the characterization of the SVF procedure as a
 8 “product,” and specifically deny that Defendants’ procedures are subject to
 9 regulation under the FDCA, but otherwise admit the remaining allegations
 10 contained in this paragraph.

11 21. Defendants admit the allegations contained in this paragraph.

12 22. Defendants deny the allegations contained in the first sentence of this
 13 paragraph and deny the characterization of the SVF procedure as a “product,” but
 14 otherwise admit the remaining allegations contained in this paragraph.

15 23. Defendants deny the first and second sentence of this paragraph, but
 16 otherwise admit the remaining allegations contained in this paragraph.

17 24. Defendants lack sufficient knowledge or information to form a belief
 18 as to the truth of the allegations in this paragraph and therefore deny them as
 19 Plaintiff does not attach the Guidelines to which it refers.

20 25. Defendants admit the allegations contained in this paragraph.

21 26. Defendants deny the characterization that the SVF is “manufactured,”
 22 and further deny the characterization of the SVF procedure as a “product,” but
 23 otherwise admit the allegations contained in this paragraph.

24 27. Defendants deny the characterization of the SVF procedure as a
 25 “product,” and further deny that the SVF is “manufactured,” but otherwise admit
 26 the remaining allegations contained in this paragraph.

27 **The CSCTC Products Are Drugs Under the FDCA**

28 28. This paragraph contains legal conclusions and does not require an

1 answer. To the extent an answer is required, Defendants deny the allegations in this
 2 paragraph. Defendants specifically deny that Defendants' procedures are subject to
 3 regulation under the FDCA.

4 29. This paragraph contains legal conclusions and does not require an
 5 answer. To the extent an answer is required, Defendants deny the allegations in this
 6 paragraph. Defendants specifically deny that Defendants' procedures are subject to
 7 regulation under the FDCA.

8 30. The first sentence of this paragraph contains legal conclusions and
 9 does not require an answer. To the extent an answer is required, Defendants deny
 10 the allegations contained in the first sentence of this paragraph. The allegations
 11 contained in the second sentence of this paragraph, including subparts (a) through
 12 (f) of this paragraph, purport to characterize the content of publicly-available
 13 sources, and Defendants specifically deny the characterization of those sources to
 14 the extent such characterizations are incomplete or inaccurate, and respectfully
 15 refer the Court to the full text of those sources. Defendants specifically deny that
 16 Defendants' procedures are subject to regulation under the FDCA.

17 31. This paragraph contains legal conclusions and does not require an
 18 answer. To the extent an answer is required, Defendants deny the allegations in this
 19 paragraph. Defendants specifically deny that Defendants' procedures are subject to
 20 regulation under the FDCA.

21 32. Defendants deny the allegations in this paragraph.

22 33. This paragraph contains legal conclusions and does not require an
 23 answer. To the extent an answer is required, Defendants deny the allegations in this
 24 paragraph. Defendants specifically deny that Defendants' procedures are subject to
 25 regulation under the FDCA.

26 **The CSCTC Products Are Biological Products Under the PHSAA**

27 34. This paragraph contains legal conclusions and does not require an
 28 answer. To the extent an answer is required, Defendants deny the allegations in this

1 paragraph. Defendants specifically deny that Defendants' procedures are subject to
2 regulation under the FDCA.

3 35. This paragraph contains legal conclusions and does not require an
4 answer. To the extent an answer is required, Defendants deny the allegations in this
5 paragraph. Defendants specifically deny that Defendants' procedures are subject to
6 regulation under the FDCA.

7 36. This paragraph contains legal conclusions and does not require an
8 answer. To the extent an answer is required, Defendants deny the allegations in this
9 paragraph. Defendants specifically deny that Defendants' procedures are subject to
10 regulation under the FDCA.

11 **The CSCTC Products Are Subject to Regulation Under the FDCA**

12 37. This paragraph contains legal conclusions and does not require an
13 answer. To the extent an answer is required, Defendants deny the allegations in this
14 paragraph. Defendants specifically deny that Defendants' procedures are subject to
15 regulation under the FDCA.

16 38. This paragraph contains legal conclusions and does not require an
17 answer. To the extent an answer is required, Defendants deny the allegations in this
18 paragraph. Defendants specifically deny that Defendants' procedures are subject to
19 regulation under the FDCA.

20 39. This paragraph contains legal conclusions and does not require an
21 answer. To the extent an answer is required, Defendants deny the allegations in this
22 paragraph. Defendants specifically deny that Defendants' procedures are subject to
23 regulation under the FDCA.

24 40. This paragraph contains legal conclusions and does not require an
25 answer. To the extent an answer is required, Defendants deny the allegations in this
26 paragraph. Defendants specifically deny that Defendants' procedures are subject to
27 regulation under the FDCA.

1 41. Defendants reference and incorporate their Answer to paragraph 7 of
2 Plaintiff's Complaint in response to the second sentence of this paragraph.
3 Defendants further respond that the remaining allegations of this paragraph contain
4 legal conclusions and do not require an answer. To the extent an answer is
5 required, Defendants deny the allegations in this paragraph. Defendants
6 specifically deny that Defendants' procedures are subject to regulation under the
7 FDCA.

8 42. This paragraph contains legal conclusions and does not require an
9 answer. To the extent an answer is required, Defendants deny the allegations in this
10 paragraph. Defendants specifically deny that Defendants' procedures are subject to
11 regulation under the FDCA.

12 43. This paragraph contains legal conclusions and does not require an
13 answer. To the extent an answer is required, Defendants deny the allegations in this
14 paragraph. Defendants specifically deny that Defendants' procedures are subject to
15 regulation under the FDCA.

16 44. This paragraph contains legal conclusions and does not require an
17 answer. To the extent an answer is required, Defendants deny the allegations in this
18 paragraph. Defendants specifically deny that Defendants' procedures are subject to
19 regulation under the FDCA.

20 45. This paragraph contains legal conclusions and does not require an
21 answer. To the extent an answer is required, Defendants deny the allegations in this
22 paragraph. Defendants specifically deny that Defendants' procedures are subject to
23 regulation under the FDCA.

24 46. This paragraph contains legal conclusions and does not require an
25 answer. To the extent an answer is required, Defendants deny the allegations in this
26 paragraph. Defendants specifically deny that Defendants' procedures are subject to
27 regulation under the FDCA.

The CSCTC Products Are Adulterated

47. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

48. Defendants admit the allegations contained in the first sentence of this paragraph. The remaining allegations of this paragraph contain legal conclusions and do not require an answer. To the extent an answer is required, Defendants deny the remaining allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

49. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

Adverse Events

50. Defendants lack sufficient knowledge or information to form a belief as to what records the FDA investigators reviewed and otherwise deny the remaining allegations in this paragraph.

51. Defendants lack sufficient knowledge or information to form a belief as to what records the FDA investigators reviewed and otherwise deny the remaining allegations in this paragraph.

The CSCTC Products Are Misbranded

52. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

53. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this

paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

54. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

Defendants Violate the FDCA

55. Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

56. Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

57. Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

Continuing Noncompliance

58. Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

59. Defendants admit they were aware that an affiliate received a Warning Letter in December 2015, deny the characterization of the SVF as a “product,” and otherwise lack sufficient knowledge or information to form a belief as to the truth of remaining allegations in this paragraph and therefore deny them. Defendants specifically deny that Defendants’ procedures are subject to regulation under the FDCA.

60. Defendants admit that Defendants Lander and Berman participated in an interview with a professor at the University of California Davis School of

1 Medicine in February 2017. The remaining allegations in this paragraph purport to
2 characterize the content of a publicly-available source, and Defendants specifically
3 deny the characterization of that source to the extent such characterization is
4 incomplete or inaccurate, and respectfully refer the Court to the full text of that
5 source.

6 61. Defendants deny the characterization of the SVF procedure as a
7 “product.” Defendants admit that in July 2017 FDA investigators conducted
8 inspections at CSCTC Rancho Mirage and CSCTC Beverly Hills. Defendants
9 further admit that during the time when FDA investigators were present at CSCTC
10 Rancho Mirage and CSCTC Beverly Hills, Defendants Berman and Lander had
11 discussions with FDA investigators, and during those discussions maintained that
12 the SVF procedure is not a drug and is not subject to regulation under the FDCA.
13 Defendants further admit that they sent written responses to the FDA regarding the
14 inspections and responding to the reports. Those written submissions, among other
15 things, demonstrate that Defendants’ practices are not subject to FDA oversight.
16 Defendants deny any remaining allegations in this paragraph, and expressly deny
17 that the FDA has jurisdiction over Defendants’ SVF procedure.

18 62. Defendants admit that Defendant Berman participated in a telephone
19 call with FDA representatives in August 2017, and further admit generally that
20 Defendant Berman stated that SVF is not a drug and is not subject to regulation
21 under the FDCA. Defendants otherwise deny that the remaining allegations
22 contained in the paragraph accurately or completely characterize the content of that
23 conversation.

24 63. Defendants admit that in August 2017, United States Marshals seized
25 five vials of ACAM2000 intended to be used by Defendants in an IRB-approved
26 safety trial for end-stage cancer patients. Defendants lack sufficient knowledge or
27 information to form a belief as to the truth of allegations contained in the second
28 sentence of this paragraph and therefore deny them. The allegations contained in

1 the third sentence of this paragraph purport to characterize the content of a
 2 publicly-available source, and Defendants specifically deny the characterization of
 3 that source to the extent such characterization is incomplete or inaccurate, and
 4 respectfully refer the Court to the full text of the source. Defendants otherwise
 5 deny the remaining allegations contained in this paragraph.

6 64. Defendants deny the characterization of the SVF procedure as a
 7 “product,” but admit that Defendants Lander and Berman communicated with the
 8 FDA in October 2017. Defendants admit the second sentence of this paragraph.
 9 Defendants specifically deny that Defendants’ procedures are subject to regulation
 10 under the FDCA.

11 65. Defendants deny the allegations in this paragraph.

12 PLAINTIFF’S PRAYER FOR RELIEF

- 13 I. Defendants deny Plaintiff is entitled to such relief.
- 14 II. Defendants deny Plaintiff is entitled to such relief.
- 15 III. Defendants deny Plaintiff is entitled to such relief.

16 AFFIRMATIVE DEFENSES

17 Further responding to the Complaint and as additional defenses thereto,
 18 Defendants assert the following affirmative defenses, without admitting any
 19 allegations of the Complaint not previously admitted, and without admitting that
 20 the Defendants bear the burden of proof or burden of persuasion on any matter set
 21 forth herein.

22 FIRST AFFIRMATIVE DEFENSE

23 This Court lacks subject matter jurisdiction to hear this action.

24 SECOND AFFIRMATIVE DEFENSE

25 The Complaint fails to state a claim upon which relief can be granted.

26 THIRD AFFIRMATIVE DEFENSE

27 Plaintiff’s claim fails because the SVF procedures fall within the “same
 28 surgical procedure exception.”

1 **FOURTH AFFIRMATIVE DEFENSE**

2 The relief sought in the Complaint is barred by the due process clause of the
3 United States Constitution.

4 **FIFTH AFFIRMATIVE DEFENSE**

5 The relief sought in the Complaint is barred as a violation of the
6 Administrative Procedure Act.

7 **SIXTH AFFIRMATIVE DEFENSE**

8 The relief sought in the Complaint is barred under the Tenth Amendment to
9 the United States Constitution.

10 **SEVENTH AFFIRMATIVE DEFENSE**

11 The relief sought in the Complaint violates patients' right to privacy
12 guaranteed by the United States Constitution.

13 **EIGHTH AFFIRMATIVE DEFENSE**

14 The relief sought in the Complaint is barred by the doctrines of laches and
15 estoppel.

16 **RESERVATION OF DEFENSES**

17 Defendants reserve the right to assert additional affirmative defenses in the
18 event that clarification of Plaintiff's allegations and/or discovery reveals any such
19 defenses to be appropriate.

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REQUEST FOR RELIEF

WHEREFORE, Defendants respectfully request that the Court render a judgment as follows:

- (a) That Plaintiff be denied all forms of relief requested in the Complaint;
- (b) That the Complaint be dismissed with prejudice and judgment entered in favor of Defendants;
- (c) That Defendants be awarded their costs and attorneys' fees to the extent allowable by law; and
- (d) For such other and further relief as the Court deems just and proper.

Dated: July 17, 2018

VENABLE LLP

By: /s/ Witt W. Chang
Celeste M. Brecht
Witt W. Chang
Attorneys for Defendants
**CALIFORNIA STEM CELL
TREATMENT CENTER, INC., CELL
SURGICAL NETWORK
CORPORATION, ELLIOT B.
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